IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **WAVE 5 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY MEMORANDUM IN FURTHER SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS OF RAGNVALD MJANGER, MD

In further support of their Motion to exclude certain opinions and testimony of Defendants' gynecology expert, Ragnvald Mjanger, M.D., ("Dr. Mjanger"), Plaintiffs state as follows.

ARGUMENT

I. Dr. Mjanger failed to apply any objective, reliable standard in offering his warning opinions in violation of *Daubert,* and lacks the basic foundational knowledge to offer these opinions

In their reply brief, Defendants first argue that Dr. Mjanger should be allowed to testify "about the specific risks of implanting mesh and whether those risks appeared in the relevant IFU" consistent with this Court's ruling regarding Dr. Flynn", and that "Plaintiffs do not appear to challenge Dr. Mjanger's competency to testify that risks that did not appear on the IFU were already commonly known to clinicians…" Def. Mem. at 2-3. Both statements are incorrect. First, it is clear from his testimony that Dr. Mjanger has not reviewed the relevant and applicable TVT IFU's, and does not know what warnings appear in them at various times during the product's history, distinguishing this case from the Court's ruling regarding Dr. Flynn. Second,

Plaintiff's do challenge Dr. Mjanger's ability to testify as to what risks were commonly known to physicians as Dr. Mjanger has repeatedly testified that he simply does not know what risks were known to physicians at various times:

> Q. Do you think that the TVT and the TVT-O IFU needs to include a warning regarding neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic, and/or abdominal area in order for it to be adequate?
>
> A. Isn't that in there? I can't recall that. I would have to look at it
>
> Q. Well, it's in there now.
>
> A. I think it should be in there. I think I've seen it in there.
>
> ***
>
> Q. So, why do you think it should be in there now but shouldn't have been in there in, say 2010?
>
> A. I didn't say that it shouldn't be back then. I just don't know enough to know whether—I don't know how much they knew it about it back then. I just don't know
>
> ***
>
> Q. So you're not offering an opinion in this case as to whether or not Ethicon and Johnson & Johnson should have included that statement in the IFU earlier than when it was added in 2015?
>
> A. **I don't know enough to make an opinion about that.** I would have to see what was available and what was known. **I just don't know that.**

(Mem, Ex. D at 231:5-15; 231:24-232:6; 233:2-10)(emphasis added). Dr. Mjanger offered similar testimony that he was unable to state when Defendants' were first aware that urge incontinence, urinary frequency, urinary retention was a potential adverse reaction, and whether or not those risks should have been included in the IFU since the day the product was first launched in 1998. *Id*. at 234:11-236:19.[1] Since he is unable to testify as to whether or not

[1] These adverse reactions were added to the IFU for the TVT products beginning in approximately May of 2015. See Exhibit A, 2015 TVT IFU, compare with Exhibit B, 2010 TVT IFU. In addition to adding a warning regarding neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, and pelvic and/or abdominal

Ethicon's own medical directors knew about certain risks at the launch of the product, he certainly cannot testify as to what other less knowledgeable doctors in the medical community knew about the product. Dr. Mjanger's own testimony confirms he lacks the foundational knowledge to opine as to what risks were warned of in the TVT IFUs at various times, and what risks were known to physicians at various times.

In addition, the opposition brief fails to identify any standard or methodology applied by Dr. Mjanger, or any standard by which Dr. Mjanger opinions on the product warnings can be objectively evaluated. That gap is fatal to Dr. Mjanger's warning opinions. In *Sanchez v. Boston Scientific Corp.*, 2014 WL 4851989 (S.D.W. Va. Sept. 29, 2014), this Court precluded an expert's warning opinions because the expert applied no standard at all to support his opinions, concluding: "Dr. Slack's subjective and conclusory approach is evidence that his opinion is based on mere speculation and personal belief." *Id.* at *32. The same applies to Dr. Mjanger, who has conducted no scientifically reliable inquiry into what physicians actually knew about the risk of the pelvic mesh devices and applied no reliable standard to conclude Ethicon's warnings are adequate.

Ethicon does not address Plaintiff's arguments that Dr. Mjanger has applied no objective standard in arriving at his opinions regarding the adequacy of the TVT IFU. Instead, defendants have conceded that "Dr. Mjanger will not opine on warnings from that perspective" (the regulatory process). Def. Mem. at 2. The problem is that while conceding this point, Ethicon identifies no objective standard which Dr. Mjanger <u>does</u> rely upon or is qualified to rely on for his opinions that Ethicon's risk information is adequate. The Defendants' position is that Dr. Mjanger should be permitted to testify of the risks inherent to all surgeries to treat SUI, and that

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area may occur, urge incontinence, urinary frequency, and urinary retention, many additional warnings regarding adverse reactions were added as well.

all of those risks are commonly known to clinicians. *Id*. at 3. Plaintiffs do not challenge Dr. Mjanger's qualifications or ability to testify as to the risks of SUI surgery. The problem arises when Dr. Mjanger attempts to speculate as to the knowledge of what other physicians know or do not know in offering the opinion that **all** of those risks are commonly known to clinicians when he has done no scientifically reliable analysis to determine whether this is actually true, and has admitted he does know this information. Plaintiffs have no objection to Dr. Mjanger testifying to the risks he perceives to patients, as the Court permitted Dr. Schull to do in the *Winebarger* decision. However, since Ethicon has not "come forward" with evidence of any objective standard Dr. Mjanger applied to opine that the warnings provided by Ethicon were adequate, his opinion that Ethicon's warnings are adequate should be precluded.

Thus, the only reliable testimony Dr. Mjanger can reliably offer is the risks of SUI surgery he perceives to patients. Where Dr. Mjanger's testimony becomes unreliable is when he makes the leap to assume that all physicians have read the same literature he has, and fully understood and retained the contents, without any reliable methodology in arriving at these conclusions. For the opinion that the risks were well known to clinicians, we simply have Dr. Mjanger's say so, which is insufficient under *Daubert*. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 157 (1999) (stating that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert").

Allowing the subjective, speculative unsupported opinions by Dr. Mjanger regarding the knowledge of the medical community concerning the risks of the pelvic mesh devices should not be permitted under *Daubert*, particularly when Dr. Mjanger has admitted he lacks knowledge on this subject. Moreover, allowing such opinions would create FRE 401 and 403 issues in these

cases, as the natural conclusion the jury will draw from this testimony is that the warning provided by defendants' was adequate, despite the expert having no foundation and applying no objective standard for that conclusion. Thus, Dr. Mjanger's warning opinions should be precluded. At the very least, the court should exclude any opinions regarding whether or not any of the warnings Ethicon added to the TVT IFU's in 2015 were necessary in order for the prior IFUs to be adequate as Dr. Mjanger has admitted he does not know enough to have an opinion on that subject.

II. Dr. Mjanger's opinions on the safety and efficacy of the TVT products should be excluded as he is not qualified, and he has applied a flawed, unreliable methodology, and has admitted that he has applied no objective standard regarding his opinions that the TVT products are safe and effective.

Dr. Mjanger is admittedly not an expert in design, and Defendants appear to concede that he is not offering any opinions on design or the design process, but rather is offering opinions regarding safety and efficacy. (Defense Brief at 5). However, by offering an opinion that the pelvic mesh products are safe and effective, Dr. Mjanger is, in effect, stating that the design of these products is safe and effective. Dr. Mjanger's use of mesh products, his experience, and his qualifications as a gynecologist do not, by themselves, uniquely qualify him to opine regarding the safety and efficacy of a medical device any more than a licensed driver is qualified to opine about the safety of a vehicle based on how it feels when he drives it and based on what she has observed when others drive it. Defendants claim that the foundation of Dr. Mjanger's design opinions (which they characterize as safety and efficacy opinions) is his personal experience as well as his analysis of the medical literature. (Def. Mem. at 8). A review of the literature does not provide sufficient basis for Dr. Mjanger to offer a reliable design opinion unless he can identify an appropriate standard that he applied. *See Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015) (finding that Dr. Schull

had not reliably applied the principles learned through his experience and the literature to the facts of this case because he had not seen any standard operating procedures or design protocols for the development of the medical device in question).

Here, in addition to admitting not being an expert in design, Dr. Mjanger has admitted he can articulate no objective standard for his opinions that the mesh devices are safe and effective:

> Q. So you can't articulate any objective standard that you're applying for an acceptable complication rate for the TVT or TVT-O to conclude that the design is reasonably safe for its intended use?
>
> A. That's for a researcher to do that.

Mem. at Ex. D, 273:4-15. According to Dr. Mjanger's analysis, there is no objective standard to declare a mesh device to be unsafe. Nowhere does Dr. Mjanger or Ethicon identify any objective standard applied by Dr. Mjanger, or by which Dr. Mjanger's opinions on safety and efficacy can be tested or objectively evaluated. As such, he should be precluded from giving any opinions related to the safety and efficacy of the mesh products.

Further, it is unknown what materials (including medical literature) Dr. Mjanger reviewed or did not review from his reliance list, including what literature he has reviewed and relied upon for his opinion that the TVT products are safe and effective:

> Q. So am I correct that as we sit here today, you don't have any kind of list of you can give me of materials that you've actually reviewed and relied upon in forming your opinions in this case?
>
> A. I cannot - - correct. I cannot give you everything that I've read.

Mem. at Ex. D, 16:19:17:4. As Dr. Mjanger's testimony makes clear that his reliance list does not contain an accurate list of the facts or data considered by him in forming his opinions as

required by F.R Civ. P 26(a)(2)(B)(ii). Dr. Mjanger testified that his reliance list was put together by counsel for Ethicon and Johnson & Johnson, and contains materials that he did not actually review.[2] This violates F.R Civ. P 26(a)(2)(B)(ii)., and leaves Plaintiffs with no understanding of the facts and materials Dr. Mjanger utilized to support his opinions, and no ability to properly cross-examine him regarding the literature he relied upon. Given that Dr. Mjanger's testimony indicates that he did not actually review or rely on any objective standard for his opinions that the TVT is safe and effective, and relies on the clinical literature, yet did not disclose what literature he relied upon, an appropriate remedy is to disallow this opinion as provided in F.R Civ. P 37(c)(1).

III. Dr. Mjanger should be precluded from testifying that polypropylene does not degrade *in vivo.*

Ethicon claims that Dr. Mjanger's opinions on degradation are based on his extensive experience combined with his review the scientific literature qualify him to opine on the mesh's reaction on the human body. Def. Mem. at 9. But Ethicon does not follow-up that assertion by providing an explanation or examples of how Dr. Mjanger ruled out these internal documents as unreliable, or the unreliability of his methodology at arriving at his conclusions in this case. Instead, it just restates Dr. Mjanger's opinion that TVT mesh does not degrade in vivo. *Id*. at 9-10. Further, it is unclear whether Dr. Mjanger's opinion is that TVT mesh does not degrade in vivo, or that it does degrade, but the degradation is not clinically significant. *Id.* In addition, Dr. Mjanger's opinions on this subject seem to be based largely on his review of "Level 1 long term studies, RCTs, systematic reviews, meta-analyses, and Cochrane reviews", yet, as discussed in section 2 above, Dr. Mjager has not identified which studies he has actually reviewed and relied upon.

[2] *Id*. at 14:22-16:17

Given that Dr. Mjanger relies heavily on the clinical literature for his opinions regarding mesh degradation, yet did not disclose what literature he relied upon, an appropriate remedy is to disallow this opinion as provided in F.R Civ. P 37(c)(1). For that reason Ethicon's reliance on this Court's ruling in *Trevino* is misplaced as the court ruled in that case that : "[i]f there are certain device-specific publications that [Plaintiffs claim that Dr. Flynn] failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination." *Trevino,* 2016 WL 2939521, at *41. In this case, the Plaintiffs are unable to ask Dr. Mjanger about publications he failed to review in cross-examination as Dr. Mjanger has failed to disclose which publications he actually did review as required by the Federal Rules. Therefore, Dr. Mjanger should be precluded from offering any opinions regarding mesh degradation.

IV. Dr. Mjanger should be precluded from offering precise statistics regarding his own personal experiences with the mesh

Dr. Mjanger proposes to opine that his own patients have not experienced a chronic inflammatory response with TVT that resulted in clinical consequences such as pain,[3] essentially proposing to testify that 100% of his patients have not experienced this particular adverse reaction. This is exactly the kind of precise statistics based on unreliable, undisclosed data with flawed analysis and methodology this court has excluded in the past. *See In re Ethicon*, 2016 WL 4542054 (S.D. W. Va. 2016). Dr. Mjanger has admitted that this opinion is essentially based on his memory, but that if he had seen inflammation he would have noted in his operative reports. Yet he has not done any kind of formalized analysis of his patients' records to see if (inflammation) was noted in their records." Mem. Ex. D at 246:19-248:7. Dr. Mjanger's

[3] Mem. Ex. D at 244:18-245:4

opinions regarding his personal experience with inflammation of mesh and pain are precise statistics based on nothing more than his memory and have not been subjected to peer-review or even any kind of formal analysis. Therefore, this court should exclude Dr. Mjanger from testifying as to his personal experiences with the mesh products in this case.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 5, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

s/ Thomas P. Cartmell